## EXHIBIT 104

## Medicaid Pharmacy Bulletin



Volume 1, No. 1

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## Medicaid Reimbursement for the Pharmacy Component of Home I.V. Therapy

Medicaid Coverage of Home Intravenous (I.V.) Therapies May Be an Effective Way to Reduce Overall Program Costs.

The growing use of home I.V. therapies has become an important issue within the Medicaid pharmacy community. These treatments, characterized by extensive use of pharmaceutical products, introduce a variety of financial, administrative and clinical issues to Medicaid pharmacy that have yet to be resolved.

A recent study of Medicaid reimbursement for home parenteral therapies in Colorado docu-

## Introductory Issue

Lederle Laboratories is pleased to present the first issue of <u>Medicaid Pharmacy Bulletin</u>. This publication is designed to assist the Medicaid pharmacy community in keeping abreast of the latest program management practices and developments in health care policy that affect Medicaid pharmacy.

We encourage you to submit information about your state's pharmacy program that you feel may be of interest to your colleagues in other Medicaid programs throughout the country. Alf-submissions, comments, questions and correspondence may be addressed to: Pamela Schaeffer, RESCON, Inc.,

8294 D Old Courthouse Road, Tysons Corner, Va. 22180 (703) 821-8110. mented that home I.V. therapies can result in significant financial savings in comparison to those administered in the traditional inpatient setting. This study, conducted by the School of Pharmacy at the University of Colorado Health Sciences Center, is described in a report entitled "The Budgetary Impact of Home Parenteral Therapy in a State Medicaid Program--A Cost Analysis and Recommendations." The cost comparisons derived from the study indicate considerable savings for patients receiving parenteral antibiotic, nutrition, pain management and hydration therapy at home instead of in the hospital. With 62 patients utilizing 1,361 days of home health care services, there was a reported savings of over \$310,000, or approximately \$5,000 per patient, in hospital costs.1

Increased Medicaid Pharmacy Budgets
Are Needed to Further Develop Home
I.V. Therapy Reimbursement Programs.

The findings of this study make a strong case for Medicaid reimbursement for home I.V. therapy. In most states, Medicaid programs do provide a degree of coverage for these treatments. However, in general, current Medicaid phar-See Medicaid, page 2

Provided as a service to Medicaid by Lederle Laboratories, Wayne, N.J.

<sup>1\*</sup>The Budgetary Impact of Home Parenteral Therapy in a State Medicaid Program—A Cost Analysis and Recommendations, "Vaughn L. Culbertson, Pharm.D., et al., School of Pharmacy, University of Colorado Health Sciences Center.

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macy budgets are not adequate to cover the myriad of products utilized in home I.V. therapy. Unless funding is sufficiently expanded to support increased utilization of home I.V. therapy, the cost-saving and clinical benefits of such treatments cannot be fully realized.

t May Be Necessary to Redistribute
Overall Medicaid Budgets to Ensure
Coverage of Home I.V. Products.

In the University of Colorado study, the authors state that it may be necessary to transfer portions of hospitalization budgets to pharmacy budgets in order to obtain the overall Medicaid program savings achievable by providing home I.V. therapy coverage. Table 1 illustrates the potential savings associated with providing TPN, parenteral pain management and parenteral hydration therapy at home as opposed to in the nospital. Since it is hospital costs that are significantly reduced by the provision of home I.V. therapy, it seems appropriate to use these savings to subsidize the additional pharmacy expenses incurred.

Many Medicaid Pharmacy Programs Lack
Specific Policies and Guidelines With Which to
Manage Home I.V. Reimbursement.

Medicaid home I.V. therapy programs are constrained not only by limited pharmacy budgets but also by a critical absence of administrative policies and procedures. For a variety of reasons, policies and procedures used to manage reimbursement for other outpatient drugs cannot be applied to the management of reimbursement for home I.V. treatment components. Among the major home I.V. management policy issues that need further consideration by the Medicaid pharmacy community are:

- The development of pricing mechanisms for home I.V. medications.
- The development of reimbursement strategies for home I.V. supplies.
- The automation of systems to process home I.V. therapy claims.
- The establishment of specific requirements to be met by providers of home I.V. products.
- The expansion of pharmacy budgets to cover home I.V. therapy products.
- 1. THE DEVELOPMENT OF PRICING MECHANISMS FOR HOME I.V. MEDICATIONS.

The Establishment of a Fair and Reasonable Pricing Methodology for Home I.V. Products is a Major Concern of Most State Medicaid Programs.

One of the major obstacles to the development of adequate home I.V. pricing methodologies is

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the fact that the dispensing of home I.V. medications is more complex than the dispensing of other outpatient drugs. Usually Medicaid pharmacy programs reimburse for outpatient drugs an amount which is determined by the individual program to be the provider's estimated acquisition cost (EAC) plus a dispensing fee. In most states, EAC is derived by a formula using the Average Wholesale Price (AWP) as the base figure.

Providers and Pharmacist Consultants Concur
That it is Not Appropriate to Apply the Same Ingredient-Based Pricing Mechanisms to Home
I.V. Medications as Those Applied to Other Outpatient Drugs.

For lack of a better alternative, some state Medicaid programs use the same ingredient-based formula they apply to other legend drugs when 3

providers are paying with volume and trade discounts. These discounts am generally not revealed in drug pricing publications such as the Red Book, the Blue Book and Medispan. Consequently, programs are reluctant to increase reimbursement for home I.V. medications, suspecting that reported costs for these substances may already be exaggerated.

Failure to Include Adequate Economic Incentives for Dispensing Home I.V. Medications May Discourage Provider Participation in These Programs.

In spite of the reservations about overcompensating providers for home I.V. medications, most

•	Table 1.	omparison of Hospital and Home LV. Therapy Costs.	ŝ
		Home Health Care Services - Colorado Medicaid	

	No. of Recipients	Total Cost of Home Treatment Billed To Medicaid	Total Cost of Comparable Treatment in Hospital	Total Net - Savings
1. TPN	3	\$ 33,520.22	\$59,850.00	\$ 26,329.78
2. Pain Ma		\$16,640.74	\$ 96,705.00	\$ 80,064.26
3. Hydratio	n 12 .	\$1,950.45	\$ 35,280.00	\$33,329.55

Source: "The Budgetary Impact of Home Parenteral Therapy in a State Medicaid Program—A Cost Analysis and Recommendations," The University of Colorado Health Sciences Center, Vaughn Culbertson, Pharm.D., et al., Table 5.

calculating reimbursement for home I.V. medications. Most pharmacist consultants are not convinced that this process reflects actual provider costs for home I.V. reimbursement.

Home I.V. treatments are frequently a combination of multiple drug entities, dispensed in varying doses and administered several times daily. Although individual doses may be minimal to moderate in quantity, over an entire treatment period large volumes of medications are generally administered. It is, therefore, difficult to estimate, based on single, daily or even weekly administrations, the purchase prices

pharmacist consultants believe that providers should be compensated at a level that accounts for the costs of preparing, storing and delivering these products. However, determinations about what these costs are and how they can be integrated into reimbursement formulas have not yet been established.

The system of adding a set dispensing fee to ingredient-based reimbursement, used to arrive at compensation for other legend drugs, clearly falls short of responding to the costs of preparing home I.V. medications. On the other hand,

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in the absence of reliable information about drug prices, many pharmacy program administrators have shied away from instituting policies specifically for home I.V. drug reimbursement. As a result, many programs resort to case by case determinations of reimbursement for these treatments.

In some states, the procedures for home I.V. therapy reimbursement are so unclear that programs choose to authorize only a small number of the requests submitted for such treatments.

A Few Medicaid Pharmacy Programs Use Systematic Methods of Arriving at Reimoursement for Home I.V. Medications.

Washington State Medicaid has developed specific formulas to calculate payment for home .V. medications. See Table 2.

Normally, the program reimburses for legend trugs at 89% of the AWP (considered to be the

EAC in Washington) plus a dispensing fee that averages out to \$3.40 per prescription. In recognition of the increased time and effort required to prepare compounded parenteral solutions, Washington Medicaid pays providers the 89% of AWP plus a compounding fee of \$1.14 for every 5 minutes spent preparing a compounded mixture (\$1.14 is the minimum amount to be paid for any compounded mixture taking less than 5 minutes to prepare).

Washington's reimbursement for enteral products does not include a compounding fee since enteral supplements are generally prepackaged by commercial suppliers. However, Washington Medicaid has acknowledged that the cost of enteral products is relatively high, particularly for local pharmacists not purchasing in sufficiently large quantities for volume discounts. The program compensates for this reduced profit-margin by reimbursing at 89% of AWP plus 25% (of 89% AWP) for commercial enteral products.

Washington State Medicaid has found that while this approach does not eliminate underpayment or overpayment in every case, on the average, and over the long run, it produces results fairly consistent with provider costs.

	able 2. Various State Medicald Pricing Stra	
	for Home Parenteral Medicatio	ns.
	Medication Pricing System	
Vasachtailean	Products from \$ '0-\$ 25	50% mark up
	Products from \$ 25-\$100 Products from \$100-\$200	45% mark up
	Products from \$200-\$300 Products from \$300 and above	35% mark up
Montana	The lower of usual and customary control of the cost of ingredictions of the cost of the c	The second second
Oregon	80% of usual and customary charge	•
Washington_	89% AWP plus a \$1.14 per 5 minute	es compounding fee.
	ed cations comments	

South Carolina Medicaid currently uses the same formula to determine payment for home I.V. medications that it uses for other outpatient drugs. Reimbursement for all legend drugs is calculated by starting with AWP, subtracting 7 1/2% and adding a \$3.40 dispensing fee. The Medicaid Pharmacy Program in South Carolina is concerned that payment based on this formula does not offer adequate economic incentives for providers of home I.V. medications. In an effort to address this perceived inadequacy, South Carolina is exploring ways to build these incentives into the formula described above, when calculating reimbursement for these drugs. To date, none of the formulas reviewed has become a matter of policy or practice, but those involved in this project feel that an appropriate methodology will soon be established.

2. THE DEVELOPMENT OF REIM-BURSEMENT STRATEGIES FOR HOME I.V. SUPPLIES.

Reimbursement for the Ancillary Products (Supplies) Used in Home I.V. Therapy Has Introduced a New Administrative Dimension to Medicaid Pharmacy Operations.

Home I.V. therapy is distinguished from other drug treatments by the different supplies required and the quantities of these supplies that are utilized. There are substantial differences from one state program to another in the extent to which reimbursement for ancillary home I.V. products is a function of the pharmacy program. Some reimburse for only the drug component and none of the ancillary supplies, others cover primarily drugs but include a few non-drug items as specified by the program, and still others provide coverage for all home I.V. therapy medications as well as all the supplies.

A Large Number of Pharmacy Programs
Have Policies That Limit Reimbursement
to Medications Only.

New York, Georgia and Texas are among the states which limit Medicaid pharmacy coverage solely to pharmaceuticals. In these and other programs governed by similar policy, the supplies and equipment associated with home

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I.V. therapy are reimbursed through other parts of the Medicaid program such as the home health or durable medical equipment departments.

Some Pharmacy Programs Have Policies
That Limit Coverage to Medications and
a Few Specified Supplies Used in Home
I.V. Therapy.

Minnesota Medicaid, for instance, restricts its pharmacy coverage to legend drugs and the containers used to hold I.V. medications. In Maryland, the pharmacy department reimburses for legend drugs as well as hypodermic needles and syringes.

Multidepartmental Responsibility for Home I.V. Product Reimbursement Can Lead to Overbilling.

In programs organized so that more than one department is billed for home I.V. products, it is sometimes possible for providers to simultaneously bill multiple departments for the same item or items. Without extensive interdepartmental communication and constant monitoring for these practices, it is likely that this activity can go unnoticed in programs with multidepartmental coverage.

A Few Pharmacy Programs Reimburse for All Medications and Supplies Utilized in Home I.V. Therapy.

Programs utilizing this approach must contend with keeping track of the variety and quantities of products involved in these treatments. These arrangements are cumbersome because all bills for products are processed through one department. However, because all billing information is examined by one department it is easier to discourage duplicate billing, to evaluate the continuity of treatment packages, and to monitor provider cost containment efforts.

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A centralized approach to reimbursing for ome I.V. products not only makes utilization reiew and monitoring more precise, but also treamlines billing procedures for providers. 
Inder this system, pharmacists who provide oth the medications and supplies for home I.V. 
nerapy (most often these are supplied by the ame provider) need only submit one bill to a 
ingle location.

Reimbursement for Supplies Represents
Major Portion of Total Medicaid Home
V. Therapy Expenses.

There is a general consensus within the Meicaid pharmacy community that there exists a ritical lack of reliable information about the rices of ancillary home I.V. supplies. Pharmaist consultants are concerned that this results a substantial amounts of money overspent on these items.

Some of these products appear in the Red Book, Blue Book and MediSpan, but none of nese publications provides a complete list of upplies and there are no other catalogues from hich to obtain this information. Medicaid ayors are left without adequate sources to enfy billing information about these products no must depend almost entirely on the honesty f providers.

Most programs rely on published AWP prices then they are available and unverified provider sports of prices when they are not. However, wen when published prices for these items an be found, the quantities in which they are urchased by providers are so enormous, it is ifficult to estimate actual acquisition costs with plume discounts.

In most states, reimbursement for supplies is ased on EAC and is calculated in much the ame way EAC for drugs is calculated, i.e., ased on AWP plus or minus a percentage of WP. For example, Washington reimburses for upplies at 89% of AWP plus 15%. Since verifiation for many of these products is difficult to

obtain, it is questionable whether or not this methodology accurately pinpoints cost plus a reasonable economic incentive.

The Medicaid Program in Minnesota utilized a unique approach to this problem. A variety of providers from throughout the state were brought together to supply the program with information about prices for home I.V. supplies. These providers produced pricing recommendations based on what they believed to be fair and reasonable prices for these products. Minnesota Medicaid refers to these recommendations when establishing reimbursement amounts for these items.

3. THE AUTOMATION OF SYSTEMS TO PROCESS HOME LV. THERAPY CLAIMS.

Computer Programs to Expedite the Process of Determining Reimbursement Have Not Yet Been Developed for Home I.V. Medications.

For the most part, automated systems are used to process outpatient drug bill claims submitted to Medicaid programs. Unfortunately, little has been done to develop automated systems to process claims for compounded medications. As previously mentioned, frequently home I.V. solutions are a combination of multiple drug entities prepared specifically for each individual patient. The individualized composition of each home I.V. medication package has inhibited development of computerized systems through which to process data for reimbursement. Consequently, reimbursement determinations for home I.V. drugs in most Medicaid programs are derived through manual calculations performed on a case by case basis. These procedures, which are both cumbersome and time-consuming, contribute to delays in compensating providers. Furthermore, they increase the likelihood of inconsistent and inaccurate reimbursement.

Standardizing the Components of Home I.V. Medication Packages May Be the Key to More Efficient and Cost Effective Reimbursement Systems.

In an effort to simplify the process of determining reimbursement for compounded home I.V. medications, a few states have initiated projects aimed at standardizing the ingredients in these solutions. Certain home I.V. treatments administered routinely do not differ radically from one compound to another. If some of these solutions can be standardized, corresponding reimbursement amounts can be attached to each one, enabling bill claims processing to be executed through a computer.

In the spring of 1986, Minnesota Medicaid launched two separate but related projects to standardize home I.V. solutions and their corresponding reimbursement amounts. One is an attempt to standardize reimbursement for the 50 most commonly requested parenteral medications and the other ventures to do the same for parenteral nutritional products.

Minnesota's experience indicates that many compounded home I.V. medications can be standardized by ingredients and that even in cases where acids and dextrose in varying quantities are added, the cost differential is insignificant. Minnesota has attached code numbers for billing purposes to each compounded mixture. Each digit in the code number represents the name, strength and volume of the products contained. The assigned code numbers and the prices that correspond to each coded compound are easily insertable into automated systems. When these systems are further refined, the tasks of calculating and monitoring reimbursement for home I.V. medications will be considerably simplified. It will also enable providers to obtain information in advance about the reimbursement amounts for these products. A secondary gain will be a reduction of time spent on negotiating payment between providers and the Medicaid program.

Other states implementing similar programs include Washington and South Carolina. It is anticipated that what will ultimately emerge from these efforts will be reasonable, adequate and consistent pricing levels for home I.V. substances, increased speed in reimbursing provid-

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ers and reduced administrative burden for Medicaid pharmacy personnel.

4. THE ESTABLISHMENT OF SPECIFIC REQUIREMENTS TO BE MET BY PROVIDERS OF HOME LY, PRODUCTS.

The Risks Associated With Intravenous
Administration of Substances Raise Serious Concerns About Provider Compliance
With Standard Preparation Procedures.

The intravenous administration of drugs carnes a higher potential for complications than does the administration of drugs through other routes. However, one risk factor associated with intravenous therapy, i.e., the development of infection, may be reduced when treatment is provided in the home rather than in the hospital The procedures used in the preparation and storage of home I.V. products have a direct bearing on the reduction of complications. It is, therefore, sound clinical as well as economic policy for Medicaid pharmacy programs to focus attention on home I.V. provider capabilities and protocols.

As a general rule, Medicaid programs mandate pharmacy providers to be licensed by the State Board of Pharmacy. Most State Boards of Pharmacy do not have specific requirements for providers of home I.V. products. The Maryland State Board of Pharmacy, however, is currently developing regulatory policies "that will affect Maryland pharmacists that dispense outpatient parenteral preparations...." The regulations will establish requirements for training and expertise, equipment and facilities, storage, record-keeping and procedures used in preparing medications.

This initiative is intended to lower the risk potential associated with home I.V. therapy. It will also serve as a cost-savings measure by potentially reducing the expense of treating complications brought on by ill-equipped providers.

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THE EXPANSION OF PHARMACY BUDGETS TO COVER HOME I.V. THERAPY PRODUCTS.

harmacy Budgets Should Be Adjusted to eet the Additional Expense of Providing ome I.V. Products.

Findings such as those reported in the Colorastudy effectively demonstrate the potential dvantages of improved and increased Medidid home I.V. coverage. It appears that substantial program savings can be a primary outcome of additional funding for such treatments. In order to maximize the benefits of Medicaid coverage for home I.V. therapy, what are also needed are refined reimbursement systems for the multitude of products involved.

In general, Medicaid pharmacy budgets have not been expanded to meet the additional expenses of home I.V. therapy. More studies are needed to illustrate to policymakers the benefits that could be achieved through further development and expansion of these programs. Until more funds are available, it may be necessary to transfer portions of Medicaid hospitalization budgets to pharmacy budgets in order to obtain the overall savings made possible by the home I.V. therapy alternative.

## Third Party Liability

ederal Regulations Require Medicaid ograms to Use the Cost Avoidance athod of Reimbursement.

lew Health Care Financing Administration CFA) regulations, effective May 12, 1986, reire that state Medicaid programs determine bether third party liability (TPL) exists, thereby suring that other insurance carriers assume in financial responsibility for Medicaid services fore Medicaid funds are expended. This nesitates the establishment of a cost avoidance stem of reimbursement by each state Medicaid program, in which providers bill other liable rd party insurers first, leaving Medicaid as payor of last resort.

ate Medicaid Programs Can Request a aiver of the Use of Cost Avoidance.

an alternative to cost avoidance is pay and ase (P&C), a system in which the provider s the Medicaid program for all claims, leaving Medicaid agency to pursue TPL. However, ites cannot use P&C unless (1) an application a waiver, including documentation of the st effectiveness of using P&C, is submitted to regional HCFA office, and (2) the state was

using P&C before November 12, 1985 (publication date of the regulations). Regulations specified January 12, 1986, as the deadline for submitting waiver applications, but some regional offices will still consider applications. These include Regions VI, VII and VIII. The goal of the regional offices is to work closely with the various state Medicaid programs to ensure compliance with federal regulations and a cost effective TPL program, according to a HCFA spokesperson.

Many States Opt to Use Pay and Chase in the Medicaid Pharmacy Program.

A number of states have submitted applications to waive cost avoidance in the pharmacy program, having determined that pay and chase is more suitable for this program. Many of these Medicaid programs reported that the Medicaid pharmacists in their states were outraged at the prospect of having to utilize cost avoidance, which they believed would substantially increase administrative costs.

## The Medicaid Pharmacy Program is Not Well Suited to Cost Avoidance.

Cost avoidance is difficult in Medicaid pharmacy since pharmacies are not adequately equipped to pursue and file large numbers of relatively inexpensive duplicate third party claims. In most cases they do not have adequate staffing or equipment to perform additional third party billing as do other providers, nor are they easily able to incorporate the added administrative burden in a cost effective manner. The pharmacy coverage offered by other third party insurers varies widely from plan to plan; while it is relatively easy to devise a system in which other insurance coverage is indicated on a Medicaid card, it is difficult to specify which drugs are included in the coverage, whether the coverage is still in effect, and whether there is a deductible to be met (in which case the Medicaid program would be liable).

In addition, "most insurance companies reimburse pharmacy services at only 70%-80% of the provider's billed charges. This would require pharmacies to bill Medicaid for the balance, resulting in the pharmacy absorbing the cost of multiple billings." The administrative costs can end up exceeding the cost of the claim, since the average cost per pharmacy claim is quite small.

Many Medicaid pharmacy directors feel that cost avoiding pharmacy claims may jeopardize provider participation in the various Medicaid programs, "if a pharmacist judges the inconvenience of billing requirements to be greater than the value of Medicaid's business."<sup>2</sup>

## Insufficient Data Result in Rejected Waivers.

Some of the waiver applications were rejected on the basis of inadequate or insufficient cost

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effectiveness data. No guidelines were published by HCFA for performing such an analysis, other than the requirement that administrative costs must be included when determining the cost effectiveness of P&C and that the P&C method of reimbursement must be as cost effective as the cost avoidance method. A few states circumvented this problem by consulting data and information already collected and compiled by other states in their region. The regional HCFA offices aided the situation by granting extensions to many states to allow more time to collect data or implement the new TPL programs.

#### HCFA Can Rescind or Amend Waivers.

Although regional HCFA offices have the authority to rescind waivers if the cost effectiveness of the TPL program changes, more often than not they will amend the waiver, thus enabling a state to change or modify its existing reimbursement method. Regulations state that individual Medicaid programs must monitor the cost effectiveness of their TPL programs and report any changes to the regional office. The main goal, however, according to spokespersons from both the Region V and Region VII HCFA offices, is overall cost savings in the Medicaid program.

<sup>1</sup> Documentation in Support of Colorado's Request to Waive Federal Requirements to Cost Avoid Nursing Home, Pharmacy, EPSDT, and HCBS Claims." Third Party Resource Section, Colorado Dept. of Social Services, March 11, 1986.

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## State Medicaid Agencies React to Proposed PHIP, CIP and Revised MAC Program

The Health Care Financing Administration's HCFA) proposed regulations to establish limits on payments for drugs in the Medicaid Program have met with considerable criticism from a majority of the state Medicaid programs.

Forty-two state Medicaid programs submitted comments to HCFA about these alternatives by the October 19th deadline for submission. Although numerous and diverse points are raised by the various state programs, their comments reflect a consensus on several key issues.

As a group, state programs appear to be parfoularly concerned about:

- the extent to which the regulation alternatives will increase administrative burden and costs,
- 2) the potential impact of the regulations on provider participation in the Medicaid Program,
- the validity of HCFA's projections about program cost savings to result from implementation of the regulations, and
- the elimination of existing and successful sost containment strategies.

## Administrative Time and Costs of CIP Could Outweigh the Benefits.

State Medicaid programs indicate that of all the alternatives outlined in the proposal, CIP is the most complex and expensive to implement. Several states point out that the amount of time and the costs involved in developing statewide screens of usual and customary charges in each state would be tremendous. Furthermore, existing auditing and billing systems would have to be revamped to accommodate the pricing system under the CIP alterna-

tive. Since the PhIP and Revised MAC pricing systems are similar to those that are currently implemented under the Federal MAC Program. It is believed that either of these would be less costly to implement than CIP. Generally, state programs feel that if any of these alternatives are adopted it should be the Revised MAC because it would have the least impact on their already limited administrative budgets.

## If Provider Participation is Reduced. Serious Access Problems Could Arise.

According to Medicaid law, HCFA is charged with the responsibility for ensuring adequate compensation for pharmacist participation in th Medicaid Program. 1 A number of comments from state Medicaid programs express concern that this statutory provision will not be upheld if the proposed regulations go into effect. It is anticipated that those pharmacies able to utilize economies of scale to purchase and sell drugs at lower prices are most likely to benefit, especially from the PhIP and CIP options. Small, independent pharmacies, unable to compete successfully under the PhIP or CIP options or to absorb the potential losses brought about by an expanded number of products subject to MAC limits, may be forced to drop out of Medicaid programs. As the Michigan Medicaid Program points out, often one or two pharmacists serve most of the Medicaid recipients

<sup>&</sup>lt;sup>1</sup> "A Memorandum of Law Applicable to Review b' dicaid Drug Reimbursement Rules," Paul Bator, P of Law, University of Chicago.

in a certain area. If primary Medicaid pharmacy providers are forced to withdraw from programs, in some areas recipients may be left without an alternative provider within reasonably close proximity.

## State Programs Doubt That Either PhIP or CIP Will Produce HCFAs Cost Saving Projections.

Given the wide range of usual and customary prices charged by the various types of providers, many state programs have concluded that CIP would require not just one screen of charges per state but rather multiple screens. Designing and monitoring such a multitiered system would constitute a significant administrative burden to which many state programs object.

In the interest of minimizing administrative burden and costs to state Medicaid programs, the CIP proposal suggests that price updates be conducted no more than once a year. While programs generally favor steps to reduce excessive administrative activities, in this case they feel that annual updates would not adequately keep up with ongoing market price fluctuations.

HCFA maintains that PhIP would necessarily generate program savings by alleviating administrative delays and costs inherent in the current MAC program. However, cost comparison data submitted to HCFA refute this assertion. For example, Michigan Medicaid calculates that it would be more costly in Michigan to administer a PhIP limit on acetaminophen with codeine 30 mg. (projected as \$77,000 annually) than to maintain its entire existing state MAC system which includes almost 100 drug entities.<sup>2</sup>

## States With Their Own Programs Are Satisfied With Their Results.

Currently, about 28 states implement their own generic substitution programs in addition to the Federal MAC. In general, state program officials are pleased with the results of their individual programs and find the prospect of installing a new system unnecessary and in some cases counterproductive.

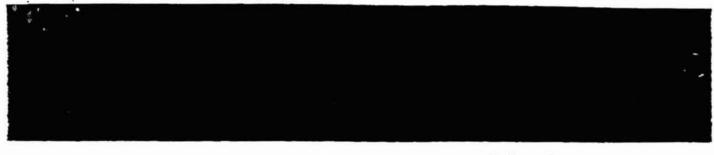
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Several states have generic substitution taws that would dilute the effect of PhIP or CIP. For example, according to Indiana law, generic substitution cannot occur unless the prescribing physician gives his consent, the patient agrees to substitute and the dispensing pharmacist believes that dispensing the generic version will not harm the patient.<sup>3</sup> If the PhIP or CIP proposals are enacted, pharmacists in Indiana will still be bound by these mandates listed above, preventing them from dispensing generics unless these conditions are met.

Because drug needs, availability and prices vary significantly from state to state, state programs tend to be in favor of state and local discretion over federal determination of pricing policies. Should the proposed regulations go into effect, states that wish to maintain their own programs will have to obtain a state waiver to do so. Waiver application requires a state to provide substantial evidence to prove that its own program will obtain at least the cost savings available through the federal program. This could, and most likely would, act as a deterrent to the development of creative cost containment initiatives at the state level.

<sup>&</sup>lt;sup>2</sup> Michigan Medicaid, Comments submitted to HCFA.

<sup>&</sup>lt;sup>3</sup> Indiana Code 16-6-8. 1-2.



## Legislative and Regulatory Update

#### FEDERAL

The Health Care Financing Administration (HCFA) has received strong recommendations from The American Pharmaceutical Association (APhA), the National Association of Chain Drug Stores (NACDS) and the National Association of Retail Druggists (NARD) to fund demonstration projects that would examine options for rembursement mechanisms in the Medicaid Prescription Drug Program. "HCFA data show more than 50% of all Medicaid paperwork is triggered by drug claims" but that these claims "constitute 6%-8% of the total program expenditures." (From Medicaid Prescription Reimbursement Reform, APhA, June 1986.)

Two alternatives were offered by APhA, NACDS and NARD: The first was a voucher system in which recipients receive numbered certificates similar to a checking account. Each roucher could represent a certain dollar amount or a specific prescription. Similar programs have been successful in Alabama and with Delaware Blue Cross/Blue Shield.

The second alternative involves the use of smart cards," similar to electronic banking cards, which would be coded with a recipient's medical history and eligibility information. This system would enable pharmacists to receive instantaneous prescription information and verification of eligibility. More importantly, though, this system would reduce paperwork, expedite payment, and potentially decrease waste, fraud and abuse. To date no action has been taken on this issue.

#### STATE

#### Michigan

The Michigan House of Representatives is considering a bill which would permit, under the

Medicaid program, medical services to be provided in the home, if charges are not greater than they would be in institutions. This bill would also require that an initial medical evaluation and medical orders be given for any services provided over a long period of time. (From IHPP "Major changes in Medicaid policy...")

New York

Under a proposed state Medicaid regulation designed to eliminate reimbursement for fraudulent sales of certain medical supplies, New York would require authorization by the state Social Services Department for specific medical supplies before payment for these items would be issued. These supplies include such things as heating pads, elastic stockings and vaporizers. North Carolina

In an attempt to reduce Medicaid pharmacy costs, North Carolina Medicaid amended its rules and regulations to define "Usual and Customary Charge." North Carolina Medicaid currently reimburses the lower of MAC, EAC or AWP plus a \$3.36 dispensing fee for each different drug dispensed during a month, or the pharmacist's usual and customary charge (U&C). U&C is now defined as the lowest price a pharmacist is willing to accept from any third party payor. For example, a pharmacist who is dispensing prescriptions at cost through a contract with an HMO must now dispense at that lower level for Medicaid recipients.

#### South Carolina

Beginning October 1, 1986, South Carolina Medicaid has increased its monthly prescription limit from three to four, on insulin syringes (S.C. Medicaid's number one prescription item), and antibiotics for home I.V. therapy. South Carolina Medicaid ensured funding for this increase by re-budgeting.

## EXHIBIT 105

# A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of Louisiana

Prepared for the Department of Health and Hospitals Baton Rouge, Louisiana

September 1999





Chapter

#### **Dispensing Cost Survey**

The two primary components for reimbursement of pharmaceuticals are drug ingredient cost and the dispensing fee. The dispensing, or professional, fee is paid to pharmacies to cover their overhead and labor costs. Federal regulations at 42 CFR 447.331-333 require states to establish a reasonable dispensing fee and to document their pharmacy reimbursement methodology in their state plan. Dispensing fees for Medicaid programs have typically been based on an analysis of costs incurred by pharmacies within the state and tend to vary somewhat from state to state. In order to determine dispensing costs incurred to dispense pharmaceuticals to Medicaid recipients in the state of Louisiana, Myers and Stauffer utilized a survey method consistent with the methodology in the Louisiana Medicaid State Plan. This method is similar to the approach which Myers and Stauffer has used as the basis for analysis of dispensing cost in over a dozen states.

#### **Methodology of the Survey**

#### **Survey Population**

The Louisiana Department of Health provided Myers and Stauffer with a list of pharmacy providers currently enrolled in the Medicaid program. Of the 1,123 pharmacies receiving cost surveys, 622 were independent pharmacies and 501 were chain pharmacies.

#### Mailing Procedures

Survey forms were mailed on February 11, 1999, to pharmacy providers currently enrolled in the Medicaid program. Each pharmacy received a copy of the cost survey (Exhibit 1), a list of instructions (Exhibit 2), a letter of explanation from Myers and Stauffer (Exhibits 3 and 4), a letter of introduction from the State of Louisiana (Exhibit 5), and a business reply envelope.



#### **Survey Participation**

Of the 1,123 surveyed pharmacies, 70 pharmacies were determined to be ineligible to participate. Providers were deemed ineligible if they had closed their pharmacy, had a change of ownership, had dispensed less than 500 Medicaid prescriptions, or had less than six months of cost data available.

Concerted efforts to encourage maximum participation were made by various parties concerned with the success of the survey. An official letter (Exhibit 5) explaining the purpose of the study was sent to the sampled pharmacy providers by the Louisiana Department of Health and Hospitals. This letter indicated that participation was mandatory and non-response was grounds for termination from the Medicaid program. The cost survey forms and instructions and a letter of explanation from Myers and Stauffer (Exhibit 3) offered pharmacy owners the option of having Myers and Stauffer complete certain sections of the survey form if copies of financial statements and/or tax returns were supplied. A toll-free telephone number was listed on the survey form, and pharmacists were urged to call to resolve any questions they had concerning completion of the survey form. An additional letter from the Louisiana Pharmacists Association (Exhibit 6) was sent encouraging participation in the survey.

The survey forms were accompanied by a flyer announcing a series of informational meetings that were held in nine locations across Louisiana (see Exhibit 7). A presentation explaining the dispensing cost survey forms was included in the meetings. Pharmacy owners and managers had the opportunity to meet with Department and Myers and Stauffer representatives and ask questions about the survey process.

By the original filing deadline of March 15, 1999, 484 cost surveys had been received. All pharmacies that had not responded by that deadline were sent a letter extending the original deadline to March 29, 1999 (Exhibit 8).

By March 29, 703 pharmacies had submitted cost surveys. In order to maximize the response rate, 340 additional cost surveys were accepted after the extended deadline.

#### Selection of Random Sample

After the survey collection process, a sample of cost surveys were chosen for review and analysis. In order to be used in the analysis, cost surveys were subjected to an intensive review process. Time constraints for the project made the use of all cost surveys impractical. Accordingly, a random sample of approximately 425 cost surveys was selected for the review process. As the selection process was entirely random and the sample size relatively large, the random sample was representative of the Louisiana Medicaid provider population.

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Many of the submitted cost surveys contained errors or were incomplete. For cost surveys with such errors or omissions, the pharmacy was contacted for clarification. There were some cases in which issues on the cost survey were not resolved in time for inclusion in the final analysis. Ultimately, 405 surveys were entered into a database and used in the analysis of dispensing costs.

The following table, 3.1, summarizes the cost survey response rate.

**Table 3.1 Pharmacies Responding to Cost Survey** 

Type of Pharmacies	Total Medicaid Participating Pharmacies	Pharmacies Exempt from Filing	Eligible Pharmacies	Cost Surveys Received	Response Rate	Pharmacies Sampled
Chain	501	12	489	484	99%	207
independent	622	58	564	489	87%	198
TOTAL	1,123	70	1,053	973	92%	405

#### **Reporting Bias**

Due to the mandatory nature of the dispensing cost survey, there is minimal risk of any reporting bias. A pharmacy's decision to file was not the result of any preconceived notion that its costs were high or low, but rather a function of the requirement imposed by the Department of Health and Hospitals.

#### **Receipt and Review Procedures**

For confidentiality purposes, each pharmacy was randomly assigned a four-digit identification number and each cost survey in the sample was carefully examined. This review identified cost surveys considered incomplete, and pharmacies submitting these cost surveys were sent a "Request for Additional Information" letter specifying the information necessary for completion (Exhibit 9). Those pharmacies not responding to the request for additional information were sent a second request for additional information. Pharmacies not responding to this second request for additional information were contacted by telephone.

#### **Field Examination Procedures**

Twenty pharmacies in the random sample were selected for a field examination. The selection was primarily random, but geographic location was taken into consideration. A letter was sent to each selected pharmacy explaining the selection process, the time period during which the field examination would take place, and the necessary data to have available. Each pharmacy was then contacted by telephone for further explanation of the field examination and confirmation of the time and date. An examination file was prepared for each of

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the 20 pharmacies containing a uniform field examination program (Exhibit 10), a copy of the completed reviewed cost survey, and other necessary work papers. Field examinations were conducted during the period June 2 through June 11, 1999.

Following the actual visit to the pharmacy, the work papers were completed by making a second examination of each file to ensure that all necessary information had been obtained. A follow-up letter was sent to each pharmacy visited, expressing appreciation for the time and cooperation of pharmacy personnel. Each work paper file was reviewed for quality assurance. Results of the 20 field examinations showed no significant bias in overstating or understating costs reported on the cost survey (Exhibit 11).

#### **Cost Finding Procedures**

Cost finding is the process of recasting cost data using rules or formulas in order to accomplish an objective. In this study, the objective is to estimate the cost of dispensing prescriptions to Medicaid recipients. To accomplish this objective, some pharmacy costs must be allocated between the prescription dispensing function and other business activities. This process identified the reasonable and allowable costs necessary for prescription dispensing to Medicaid recipients.

Most pharmacies are also engaged in lines of business other than the dispensing of prescription drugs. For example, many pharmacies have a retail business with sales of over-the-counter (OTC) drugs and other non-medical items. Some pharmacies are involved in the sale of durable medical equipment. The existence of these other lines of business necessitate that procedures be taken to isolate the costs involved in the prescription dispensing function of the pharmacy.

Dispensing cost consists of two components: overhead and labor. The cost finding rules employed to determine each of these components are described in the following sections.

#### **Overhead Costs**

Overhead cost per prescription was calculated by summing the allocated overhead of each pharmacy and dividing this sum by the number of prescriptions dispensed. Overhead expenses originally reported for the entire pharmacy were allocated to the prescription department based on either:

- The sales ratio (prescription sales / total sales),
- The area ratio (prescription department floor space (in square feet) / total floor space),
- All (100%), or
- None.



Overhead costs that were considered entirely prescription-related include:

- Prescription department fees.
- Dues and publications.
- Prescription delivery expense.
- Prescription computer expense.
- Prescription containers and labels. (For many pharmacies the costs associated with prescription containers is captured in their cost of goods. Subsequently, it was often the case that a pharmacy was unable to report expenses for prescription containers. In order to maintain consistency, a standardized allowance for prescription containers was determined in conjunction with a consultant pharmacist. See Exhibit 12.)
- Certain other expenses that were separately identified on lines 27-29² (see the cost survey in Exhibit 1).

Overhead costs that were not allocated as a prescription expense include:

- Income taxes<sup>3</sup>.
- Bad debts<sup>4</sup>.
- Advertising.
- Contributions<sup>5</sup>.

Certain costs reported on Lines 27, 28, and 29 were occasionally excluded. An example is freight expense, which usually relates only to nonprescription purchases or cost of goods sold.

The remainder of the costs was assumed to be related to *both prescription and nonprescription sales*. Joint cost allocation is necessary to avoid understating or overstating the cost of filling a prescription.

<sup>&</sup>lt;sup>5</sup> Individual proprietors and partners are not allowed to deduct contributions as a business expense for federal income tax purposes. Any contributions made by their business are deducted along with personal contributions as itemized deductions. However, corporations are allowed to deduct contributions as a business expense for federal income tax purposes. Thus, while Line 19 on the cost report recorded the business contributions of a corporation, none of these costs were allocated as a prescription expense. This, again, afforded equal treatment for each type of ownership.



<sup>&</sup>lt;sup>2</sup> Expenses that were considered entirely prescription-related were transferred to Lines16 or 28. One example is continuing professional education for a pharmacist.

<sup>&</sup>lt;sup>3</sup> Income taxes are not considered an operational cost because they are based upon the profit of the pharmacy operation. Although a separate line was provided for the state income taxes of corporate filers, it was not allowed as a prescription cost in order to afford equal treatment to each pharmacy, regardless of the type of ownership.

<sup>&</sup>lt;sup>4</sup> Bad debts were not considered a prescription-related expense since they are revenue offsets arising through an accrual recognition of revenues which are later found to be not collectible. Disallowing this expense also afforded equal treatment to providers, irrespective of their method of accounting.

Those overhead costs allocated on the ratio of the *floor space* (as previously defined) include:

- Depreciation.
- Real estate taxes.
- Rent.
- Repairs.
- Utilities.

The costs in these categories were considered a function of floor space. For example, the larger the facility, the higher the rent, if other factors are considered equal. The floor space ratio was increased by 50 percent from that reported on the original cost survey to allow for waiting area for patients and prescription department office area. The resulting ratio was adjusted downward, when necessary, not to exceed the sales ratio (in order to avoid allocating 100% of these costs in the rare instance where the prescription department occupies the majority of the area of the store).

Overhead costs allocated using the sales ratio include:

- Personal property taxes.
- Other taxes.
- Insurance.
- Interest.
- Accounting and legal fees.
- Telephone and supplies.

#### **Labor Costs**

Labor costs are calculated by allocating total salaries, payroll taxes, and benefits based on the percent of time spent in the prescription department. The allocations for each labor category were summed and then divided by the number of prescriptions dispensed to calculate labor cost per prescription. There are various classifications of salaries and wages requested on the cost survey (Lines 31-44) due to the different cost treatment given to each labor classification.

The total salaries, payroll taxes, and benefits of employee pharmacists (Lines 34-38) were multiplied by a factor based upon the percent of prescription time. Although some employee pharmacists spent a portion of their time performing nonprescription duties, it was assumed that their economic productivity when performing nonprescription functions was less than their productivity when performing prescription duties. Therefore, a higher percentage of salaries, payroll

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taxes, and benefits was allocated to prescription labor costs than would have been if a simple percent of time allocation was utilized. Specifically, the percent of prescription time indicated was multiplied by two and divided by the percent of prescription time plus one.

The allocation of salaries, payroll taxes, and benefits for all other prescription employees (Lines 39-43)

#### An Example:

An employee pharmacist spends 90 percent of their time in the prescription department. The 90 percent factor would be modified to 95 percent:

$$\frac{(2)(.9)}{(1+.9)}$$

Thus, 95 percent of the reported salaries, payroll taxes, and benefits would be allocated to the prescription department. It should be noted that most employee pharmacists spent 100 percent of their time in the prescription department.

was based directly upon the percentage of time spent in the prescription department as indicated on the individual cost survey. For example, if the reported percentage of prescription time was 75 percent and total salaries were \$10,000, then the allocated prescription cost would be \$7,500.

#### **Owner Compensation Issues**

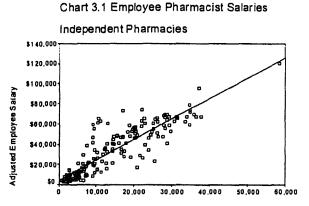
The allocation of salaries, payroll taxes, and benefits of the owner pharmacists (Lines 31-33) was based upon the same modified percentage as that used for employee pharmacists. However, limitations were placed upon the allocated salaries, payroll taxes, and benefits of owner pharmacists. Since amounts shown for owner pharmacists are not historical costs that have arisen from arm's length negotiations, they are not similar to other costs. A pharmacy owner has a different attitude toward other expenses than toward his/her own salary. In fact, owners often pay themselves above the market costs of securing the services of an employee pharmacist. This excess effectively represents a withdrawal of business profits, not a cost of dispensing. Some owners may underpay themselves for business reasons, which would also misrepresent the true dispensing cost.

Another factor considered in determining the allocation of owner's salaries was the variability in productivity. For example, one owner pharmacist may dispense 30,000 prescriptions per year while another may dispense 5,000. Those owner pharmacists who dispensed a greater number of prescriptions were allowed a higher salary than were owner pharmacists who dispensed a smaller number of prescriptions. Since variance is not nearly as great with respect to employee pharmacists, the owner pharmacist's salary was subjected to limits based upon employee pharmacists' salaries per prescription.



#### **Determining Owner Compensation Allowances**

To estimate the cost that would have been incurred had an employee been hired to perform the prescription-related functions actually performed by the owner, a bivariate plot technique was used. A bivariate plot shows the correlation between an independent (predictor) variable and a dependent (predicted) variable. The upper and lower limits on owner pharmacist salary were determined from a bivariate



Number of Prescriptions Dispensed by Employee Pharmacists

regression (Chart 3.1)<sup>6</sup>. The resulting regression equation to predict pharmacist labor cost at varying amounts of work performed is:

#### Labor cost = \$2.033 X (number of prescriptions dispensed) + \$4,072

This equation was used as a lower limit for allocating owner pharmacist costs. Adding one standard deviation (\$10,981) to the above equation set the upper limit. An additional constraint is a \$73,217 maximum annual salary. This amount was set at the 75<sup>th</sup> percentile of annual salary for full time employee pharmacists at independent pharmacies. Thus, the amount of owner's salary allocated to prescription costs was limited to \$2.033 times the number of prescriptions dispensed by the owner<sup>7</sup> plus \$15,053, not to exceed \$73,217.

There is no reason to believe that managerial or clerical duties performed by the nonpharmacist owners were more valuable to the prescription dispensing function than for other functions. As with other owners, the amount shown for salaries, payroll taxes, and benefits was not a result of arm's length negotiations. Therefore, an upper limit of \$20,000 and a lower limit of \$10,000 were placed upon these prescription costs. These limits were chosen based on experience in prior surveys. No adjustment was made to the percentage of prescription time factor for owner nonpharmacists (Lines 31-33).

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<sup>&</sup>lt;sup>6</sup> Employee pharmacist salary per prescription was used to set limitations on owner pharmacist salary estimates due to the "arm's length" nature and lack of variance in employee productivity compared with owner productivity.

<sup>&</sup>lt;sup>7</sup> The number of prescriptions filled by the owner pharmacist was determined by multiplying the percent of owner-filled prescriptions (Lines 31-33 of the cost report) by the total number of prescriptions dispensed (Line k).

#### **Overall Labor Cost Constraints**

An overall constraint was placed on the proportion of total reported labor that could be allocated as prescription labor. The constraint assumes that a functional relationship exists between the proportion of allocated prescription labor to total labor and the proportion of prescription sales to total sales. It is also assumed that a higher input of labor costs is necessary to generate prescription sales than nonprescription sales, within limits.

The parameters of the applied labor constraint are based upon an examination of data submitted by all pharmacies. These parameters are set in such a way that any resulting adjustment affects only those pharmacies with a percentage of prescription labor deemed unreasonable. For instance, the constraint would come into play for an operation that reported 75 percent pharmacy sales and 100 percent pharmacy labor (obviously, some labor must be devoted to generating the 25 percent nonprescription sales).

To determine the maximum percentage of total labor allowed, the following calculation was made:

$$\frac{0.3(Sales\ Ratio)}{0.1+(0.2)(Sales\ Ratio)}$$

#### **Inflation Factors**

All allocated costs for overhead and labor were totaled and multiplied by an inflation factor. Inflation factors are intended to reflect cost changes from the middle of the reporting period of a particular pharmacy to a common fiscal period ending June 30, 1999. As specified in the Louisiana Medicaid State Plan, the midpoint and terminal month indices used were taken from the U. S. Government Consumer Price Index (CPI), Southern Region, Urban Consumer (see Exhibit 13).

The use of inflation factors is necessary in order for pharmacy cost data from various fiscal years to be compared uniformly. Recent experience with pharmacy cost studies has indicated that the CPI may tend to overstate increases in dispensing cost over an extended time. This appears to be the result of increased cost containment pressures exerted on retail pharmacies by reduced reimbursement from managed care entities.

#### **Analysis and Findings**

The dispensing costs for all pharmacies in the sample are summarized in the tables and paragraphs following. We present the findings for all pharmacies in the sample collectively, and also for subsets of the sample based on pharmacy characteristics.

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There are several statistical measurements that may be used to express the central tendency of a distribution, the most common of which are the average, or mean, and the median (see sidebar). Our findings are presented in the forms of means and medians, both raw and weighted.

In many real world settings such as this dispensing cost survey, statistical "outliers" are a common occurrence. These outlier pharmacies have dispensing costs that are not typical of the majority of pharmacies. Medians are often preferred to averages in situations where the magnitude of outlier values results in an arithmetic average that does not represent what we think of as "average" or normal in the common sense. The measurement that is the most ideally suited for determining the typical cost of dispensing prescriptions to Medicaid recipients is the median weighted by Medicaid volume.

For all pharmacies in the sample, our findings are presented in Table 3.2.

#### Different Measures of Central Tendency:

Unweighted mean: simply the average cost for each pharmacy.

Weighted mean: the average cost of all prescriptions dispensed by pharmacies included in the sample, weighted by prescription volume. This implies that low volume pharmacies have a smaller impact on the weighted average than high volume pharmacies. This approach, in effect, sums all costs in the sample and divides that sum by the total of all prescriptions in the sample. The weighting factor can be either total prescription volume or Medicaid prescription volume.

Median: the value that divides a set of observations (such as dispensing cost) in half. In the case of this survey, the median is the dispensing cost such that the cost of one half of the pharmacies in the set are less than or equal to the median and the dispensing costs of the other half are greater than or equal to the median.

Weighted Median: This is determined by finding the pharmacy observation that encompasses the middle value prescription. The implication is that one half of the prescriptions were dispensed at a cost of the weighted median or less, and one half were dispensed at the cost of the weighted median or more.

For example, there were 4,205,203 Medicaid prescriptions dispensed by the 405 pharmacies in the sample. If the pharmacies were arrayed in order of dispensing cost, the median weighted by Medicaid volume, is the dispensing cost of the pharmacy the dispensed the middle, or 2,102,602<sup>nd</sup> prescription.

Table 3.2 Cost Per Prescription – All Pharmacies

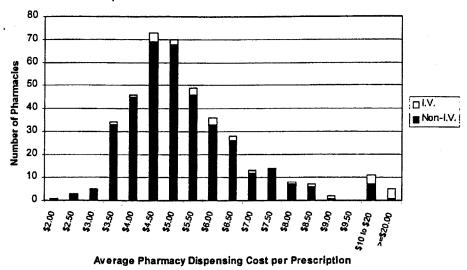
	Dispensing Cost
Median Weighted by Medicaid Volume	\$5.15
Median Weighted by Total Volume	\$5.07
Median	\$5.28
Unweighted Mean	\$6.45
Mean Weighted by Medicaid Volume	\$5.52
Mean Weighted by Total Volume	\$5.39

(Dispensing Costs have been inflated to the common point of June 30, 1999)

Chart 3.1 is a histogram of the dispensing cost for all pharmacies in the sample. There was a large disparity between the highest, \$152.55, and lowest, \$2.18, dispensing cost observed for pharmacies in the sample. The majority of pharmacies (238), however, had dispensing costs in the range of \$4.00 to \$6.00.







The most significant characteristic which affected pharmacy dispensing cost was the provision of intravenous (I.V.) solutions. Our analysis revealed significantly higher costs of dispensing is associated with the 28 pharmacies in the sample that provided this service.

In every pharmacy dispensing study where information on I.V. solution dispensing activity has been collected by Myers and Stauffer, such activity has been found to be associated with higher dispensing costs. Discussions with pharmacists providing I.V. solutions indicate that the activities and costs involved in filling I.V. prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy. The reasons for this difference include:

- costs of special equipment for mixing and storage of I.V. solutions;
- higher direct labor costs because most I.V. prescriptions must be mixed in the pharmacy, whereas the manual activities to fill a non-I.V. prescription are mainly limited to counting pills (or vials, etc.) and printing and affixing the label; and
- a pharmacy may mix and deliver many "dispensings" of a daily I.V. solution from a single prescription, thus incurring additional costs spread over a smaller number of prescriptions.

This latter factor, in particular, can have a dramatic impact on increasing a pharmacy's apparent cost per prescription.



The differences in dispensing costs which were observed for providers of I.V. services compared to those pharmacies which did not offer I.V. services are summarized in Table 3.3.

Table 3.3 Cost Per Prescription - I.V. Versus non I.V. Pharmacies

	Number of	Unweighted Mean Total	Standard	Mean Total Cost Weighted by
Type of Pharmacy	Pharmacies	Cost	Deviation	Total Volume
Pharmacies Dispensing I.V. Prescriptions	28	\$18.57	\$32.86	\$8.97
Pharmacies Not Dispensing I.V. Prescriptions	377	\$5.55	\$1.76	\$5.14

(Dispensing Costs have been inflated to the common point of June 30, 1999)

Based on our cost findings, it must be concluded that the costs incurred to dispense I.V. prescriptions are not representative of the costs incurred by a general pharmacy. If the costs of I.V. services were to be included in the computation of an average or median dispensing cost that was then used to establish a reimbursement rate, the effect would be to pay approximately 93% of pharmacies an additional allowance for a service they never provided. And, for those pharmacies providing I.V. services, the marginal increase in the fee would be immaterial in relation to the cost of actually dispensing an I.V. prescription. Consequently, many of the analyses which follow, exclude these providers which had dispensed I.V. prescriptions. Table 3.4 restates some of the measurements noted in Table 3.2 excluding pharmacies that dispensed I.V. prescriptions.

Table 3.4 Cost Per Prescription - Excluding I.V. Pharmacies

	Dispensing Cost
Median Weighted by Medicaid Volume	\$5.07
Median Weighted by Total Volume	\$5.03
Median	\$5.23
Raw Mean	\$5.55
Mean Weighted by Medicaid Volume	\$5.19
Mean Weighted by Total Volume	\$5.14

(Dispensing Costs have been inflated to the common point of June 30, 1999)

Atthough typical dispensing fees reimburse less than the dispensing costs of I.V. pharmacies, they are generally able to break even based on the margin allowed on ingredient cost reimbursement.



#### **Analysis of Pharmacy Characteristics**

Responding pharmacies were categorized into various groups of interest and their dispensing costs analyzed to determine statistical significance. These characteristics include:

- Chain versus independent pharmacy affiliation.
- Urban versus rural pharmacy location.
- Type of pharmacy ownership.
- Total prescription volume.
- Total Medicaid volume.
- Medicaid volume as a percent of total volume.
- Provision of unit dose dispensing services.

For reasons previously described, these analyses are limited to those pharmacies that did not provide I.V. services. All costs referred to in these analyses have been inflation adjusted to the common point of June 30, 1999.

One way to determine the statistical significance of differences in dispensing cost between the pharmacies classified by the above referenced characteristics is through the use of a *t*-test. The sample data may show that a certain group of pharmacies has a sample mean lower or higher than another group. Recognizing that the data only represents a sample, a *t*-test is a statistical technique that seeks to determine if the findings are strong enough that a similar relationship can be expected to exist for the entire population. The *t*-test takes into consideration the sample's size, mean, and underlying variance.

1) Chain Versus Independent Pharmacy Affiliation

Of the 377 pharmacies in the sample that did not dispense I.V. prescriptions, 170 were independent pharmacies and 207 were chain pharmacies.

Table 3.5 Chain Versus Independent Pharmacies

				Median Weighted
Type of	Number	Unweighted	Standard	by Medicaid
Pharmacy	of Stores	Mean Cost	<b>Deviation of Cost</b>	Volume
Independent	170	\$5.45	\$2.11	\$5.08
Chain	207	\$5.64	\$1.41	\$5.03

The use of a *t*-test indicates that the difference in the raw means is not statistically significant (at the 5% level of significance). This means that there is insufficient evidence in the *sample* data to support the contention that there is a chain versus

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independent dispensing cost differential for the population of *all* chain and independent pharmacies.

#### 2) Urban Versus Rural Pharmacy Location

Myers and Stauffer used the zip code of each pharmacy to determine if it was located in a Metropolitan Statistical Area (MSA) as used by the federal Health Care Finance Administration (HCFA). Those in an MSA were considered to be urban, and those not in an MSA were considered rural.

Table 3.6 Urban Versus Rural Pharmacy Location

			Standard	Median Weighted by
Location of Pharmacy	Number of Stores	Unweighted Mean Cost	Deviation of Cost	Medicaid Volume
Urban	263	\$5.59	\$1.76	\$5.17
Rural	114	\$5.47	\$1.77	\$4.92

Again, the use of a *t*-test indicates that the difference in the raw means is not statistically significant (at the 5% level of significance).

As an additional analysis of pharmacy dispensing cost by location, pharmacies were grouped by Medicaid region.

Table 3.7 Dispensing Costs by Medicaid Region

Table of Disposioning Cooks by incultation (1991)						
Location of Pharmacy	Number of	Unweighted Mean	Standard			
(Medicaid Region)	Stores	Cost	Deviation of Cost			
Region I, New Orleans	72	\$5.84	\$1.95			
Region II, Baton Rouge	45	\$5.69	\$2.66			
Region III, Thibodaux	32	\$5.67	\$1.87			
Region IV, Lafayette	61	\$5.43	\$1.22			
Region V, Lake Charles	30	\$5.46	\$1.01			
Region VI, Alexandria	32	\$5.34	\$2.03			
Region VII, Shreveport	37	\$5.47	\$1.16			
Region VIII, Monroe	36	\$5.74	\$1.65			
Region IX, Mandeville	30	\$5.04	\$1.52			
Out of State	2	\$4.94	\$0.03			

Some of the differences observed in the regional breakdown of dispensing cost are statistically significant (at the 5% level of significance). For example the two extremes, Region I, New Orleans, and Region IX, Mandeville, have a statistically significant difference in dispensing costs. Other differences, such as between the New Orleans and Baton Rouge regions, are not significant.



#### 3) Type of Pharmacy Ownership

Pharmacies reported their ownership as being

- sole proprietor,
- partnership, or
- corporation.

**Table 3.8 Pharmacy Ownership** 

Ownership Structure	Number	Unweighted Mean	Standard Deviation of
of Pharmacy	of Stores	Cost	Cost
Sole Proprietor	38	\$5.25	\$1.26
Partnership	54	\$5.19	\$0.99
Corporation	283	\$5.61	\$1.81

The majority, 75%, of pharmacies had a corporate business structure. Differences in dispensing costs among these types of ownership structures were not statistically significant (at the 5% level of significance).

#### 4) Total Prescription Volume

Pharmacies were classified into meaningful groups based upon their differences in total prescription volume. Dispensing costs were then analyzed based upon these volume classifications.

**Table 3.9 Pharmacy Total Annual Prescription Volume** 

Total Annual Prescription Volume of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
0 to 14,999	37	\$7.69	\$3.29
15,000 to 24,999	82	\$6.09	\$1.57
25,000 to 49,999	124	\$5.25	\$1.30
50,000 to 79,999	78	\$4.91	\$0.93
80,000 and Higher	56	\$4.94	\$0.91

There is a significant correlation between a pharmacy's total prescription volume and the dispensing cost per prescription. For all categories noted above, with the exception of the two highest volume categories, differences in the mean dispensing cost were statistically significant (at the 5% level of significance). This result is not surprising because many of the costs associated with any business, included the dispensing of prescriptions, are fixed in nature, and do not vary significantly with increased volume. For stores with a higher total prescription volume, these fixed costs are spread over a greater number of prescriptions resulting in lower costs per prescription.



#### 5) Total Medicaid Volume

Pharmacies were also classified based upon their Medicaid volume. Medicaid volume for calendar year 1998 was supplied to Myers and Stauffer by the Department's fiscal agent, UNISYS.

**Table 3.10 Pharmacy Annual Medicaid Prescription Volume** 

Annual Medicaid Prescription Volume	Number of	Unweighted Mean	Standard Deviation
of Pharmacy	Stores	Cost	of Cost
0 to 2,999	76	\$6.48	\$2.58
3,000 to 14,999	228	\$5.50	\$1.43
15,000 and Higher	73	\$4.76	\$1.13

Again, for all of the classifications shown, the differences in the mean dispensing cost were found to be statistically significant (at the 5% level of significance). It should be noted, however, that there is a correlation between Medicaid volume and total prescription volume. The relationship noted with regard to Medicaid volume, is a function of total prescription volume rather than Medicaid volume alone.

#### 6) Medicaid Volume as a Percent of Total Volume

A better measure of the effect of a provider's Medicaid volume was to use Medicaid volume as a percent of total volume. To facilitate this analysis, pharmacies were arrayed into meaningful classifications of Medicaid utilization.

Table 3.11 Pharmacy Medicaid Utilization Ratio

Medicaid Proposintian	nodia odnizate	111111111111111111111111111111111111111	
Medicaid Prescription Volume as a Percent of	Number of	Unweighted Mean	Standard Deviation
Total Volume	Stores	Cost	of Cost
0.0% to 9.9%	100	\$5.59	\$1.60
10.0% to 39.9%	195	\$5.40	\$1.40
40.0% and Higher	82	\$5.75	\$2.56

The differences in the sample means observed here were not statistically significant. This important result indicates that the sample data does not support the contention that there are higher or lower costs associated with a pharmacy's Medicaid utilization.

#### 7) Provision of Unit Dose Dispensing Services

Pharmacies were classified by whether or not they provided prescription drugs in unit dose packaging.

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**Table 3.12 Provision of Unit Dose Prescription Services** 

			Standard Deviation	Mean Weighted	Mean Weighted
Type of	Number	Unweighted	of Cost	by Total Volume	by Medicaid
Pharmacy	of Stores	Mean Cost		VOIGITIE	Volume
Provides Unit Dose Services	135	\$5.27	\$1.44	\$5.12	\$5.20
Does Not Provide Unit Dose Services	242	\$5.71	\$1.91	\$5.15	\$5.18

Without further analysis, the results shown in Table 3.12 indicate that there is a significantly higher dispensing cost associated with pharmacies that do *not* dispense unit dose prescriptions. However, as the weighted means suggest, the raw means are somewhat skewed by providers with relatively low volumes. A more reasonable conclusion would be that the provision of unit dose dispensing services does not produce a significant differential in dispensing costs.

The analyses described above tested for significance differences in cost by analyzing one pharmacy attribute at a time. A more sophisticated method to analyze the impact of pharmacy characteristics upon dispensing cost is to use a multivariate regression analysis. In such an analysis, it is possible to control for factors known to affect dispensing cost, such as total prescription volume, and determine if other factors have a significant impact dispensing cost. It is possible for an attribute to be not statistically significant in a *t*-test, but still be shown to have some effect on dispensing cost in a multivariate analysis. For further discussion of the multivariate analyses performed on the dispensing cost data, see Appendix A.

#### **Components of Cost**

Information on prescription dispensing cost was collected on the cost survey in individual expense categories. We analyzed the various components of the average dispensing cost for the pharmacies in the sample. Table 3.13 and Charts 3.2 and 3.3 display the various cost components of the mean costs for pharmacies in the sample. Mean costs were weighted by total prescription volume, and for this presentation pharmacies dispensing I.V. prescriptions were excluded.

Expenses were classified as follows:

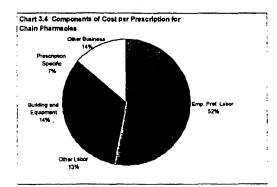
- Owner professional labor owner's labor costs were subject to constraints in recognition of its special circumstances as previously noted.
- Employee professional labor consists of employee pharmacists.

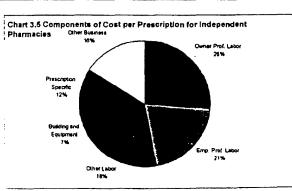


- Other labor includes the cost of delivery persons, interns, technicians, clerks and any other employee with time spent performing the prescription function of the pharmacy.
- Building and equipment expense includes depreciation, rent, ownership costs, repairs, utilities and any other expenses related to building and equipment.
- Prescription-specific expense includes pharmacist-related dues and subscriptions, prescription containers and labels, prescription-specific computer expenses, continuing education, prescription fees<sup>9</sup>, and any other expenses that are unique to the prescription dispensing business.
- Other business expenses consists of all other expenses that were allocated to the prescription dispensing function of the pharmacy including interest, insurance, telephone, and legal and professional fees.

**Table 3.13 Components of Prescription Dispensing Cost** 

Type of Expense	Chain Pharmacies	Independent Pharmacies
Owner Professional Labor	\$0.00	\$1.32
Employee Professional Labor	\$2.78	\$1.02
Other Labor	\$0.69	\$0.89
Building and Equipment	\$0.71	\$0.37
Prescription Specific Expenses	\$0.35	\$0.57
Other Business Expenses	\$0.71	\$0.79
Total	\$5.23	\$4.97





<sup>&</sup>lt;sup>9</sup> The Department of Health and Hospitals levies a \$0.10 per prescription fee on Louisiana pharmacies. Some pharmacies reported the fee on the cost survey as an expense to the pharmacy. Others treated the prescription fee similar to sales tax, an expense passed on to the consumer, and consequently not an expense to the pharmacy. In some cases, it was difficult to determine if the pharmacy had included or excluded the expense related to this fee. As far as it was possible to do so, the survey results include expense related to this fee.

Clearly, the single largest component of cost is labor with both independents and chain pharmacies spending 65% of their overall prescription costs on labor related costs. Chain pharmacies tend to have a larger portion of their labor costs devoted to professional labor compared to independents which tended to have higher "other" labor.

#### Summary

To summarize, the significant findings from the dispensing cost survey are as follows:

- The median cost to dispense a prescription (weighted by Medicaid prescriptions and inflated to June 30, 1999) is \$5.07.
- No association was found between dispensing cost and unit-dose packaging, or other measures of long term care dispensing activity.
- No significant difference was found between the dispensing costs of urban versus rural pharmacies.
- No significant difference was found between the dispensing costs of independent and chain pharmacies.

Table 3.14 Inflation Adjusted Median Dispensing Cost

Period	Midpoint	Inflation Adjusted <sup>A</sup> Median <sup>B</sup> Dispensing Cost
State Fiscal Year 1999	12/31/1998	\$5.00
Calendar Year 1999	6/30/1999	\$5.07
State Fiscal Year 2000	12/31/1999	\$5.14
Calendar Year 2000	6/30/2000	\$5.22
State Fiscal Year 2001	12/31/2000	\$5.29

Inflation factors to June 30, 1999 are based on the CPI, Southern Region, Urban Consumer. Future inflation projections are based on the CPI, All Urban, as published in Health Care Cost Review, First Quarter 1999 by Standard & Poor's DRI.

B Weighted by Medicaid prescription volume.

Myers and Stauffer